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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,318	ALDAZ ET AL.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *3,4,6,7,13,14,16,17,27,28,30,31 and 34-354* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,5,8-12,15,18-26,29,32,33,36 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Subgroup A and SEQ ID No. 1 and 2 (which reads on claims, 1-2, 5, 8-12, 15, 18-26, 29, 32, 33, 36 and 39) in the reply filed on 5/21/04 is acknowledged.

Claims 3-4, 6-7, 13-14, 16-17, 27-28, 30-31, 34-35, 37-38 and 40-73 are withdrawn from consideration.

Priority

The currently pending claims have priority to 10/13/00.

Information Disclosure Statement

The IDS filed 2/7/02 has been considered and an initialed copy of the PTO-1449 is enclosed.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The specification has incorrect reference to SEQ ID No 1 and 2. For example, the specification reference to the nucleic acid encoding SEQ ID NO. 2. However, SEQ ID NO. 2 is a DNA sequence not a protein sequence. Correction is required.

For the purposes of this action, any reference to SEQ ID NO. 1 will be interpreted as meaning SEQ ID NO. 2 and visa-versa..

Claim Rejections - 35 USC § 112

Claims 1-2, 5, 8-12, 15, 18-26, 29, 32, 33, 36 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to reference to the nucleic acid encoding SEQ ID NO. 2. However, SEQ ID NO. 2 is a DNA sequence not a protein sequence. Similarly, the claims refer to a polynucleotide comprising SEQ ID NO. 1. SEQ ID NO. 1 is a protein sequence not a DNA sequence. **For the purposes of this action, any reference to SEQ ID NO. 1 will be interpreted as meaning SEQ ID NO. 2 and visa-versa..**

Claims 1, 8-11, 20-25, 32 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated DNA molecules
a) comprising SEQ ID NO: 2 and
b) comprising a sequence having at least 70% identity to SEQ ID NO. 2 (as defined by page 28, lines 10-16 of the specification).

The claims are further drawn to vectors comprising the above sequences and host cells transfected with them.

The specification discloses an isolated cDNA sequence, SEQ ID NO: 2, which encodes a polypeptide sequence, SEQ ID NO. 1. The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be acheived by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5 and 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bednarek et al Cancer Research vol. 60 p. 2140 (4/00) .

This reference discloses the ORF of WWOX which is 1245 bp (which reads on SEQ ID No. 2 of the instant invention) and 414 amino acids (which reads on SEQ ID NO. 1 of the instant invention (abstract).

Claims 1-2, 5, 8-12, 15, 18-20, 25-26 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/44466 (priority to PQ4711, filed 12/16/99).

This reference discloses SEQ ID NO. 28 and 29 which read on SEQ ID NO. 2 of the instant invention and also discloses SEQ ID NO. 32 and 33 which reads on SEQ ID NO. 1 of the instant invention. Claims 50 and 51 disclose the use of recombinant host cells to express the protein using the DNA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 5, 8-12, 15, 18-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/44466 (priority to PQ4711, filed 12/16/99) in view of applicant's admission on pages 37-40 of the specification.

The primary reference has been discussed above.

The only different between the instant invention and the reference is that the reference does not disclose promoters and vectors.

On pages 37-40 of the specification, applicant discloses that the claims promoters and vectors are known in the art of expression.

In view of applicant's admission, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use any know promotor or vector to express the protein of the primary reference, with the expected benefit of expressing the protein.

Claims 1-2 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/12544 (priority to 8/7/00).

This reference discloses WWOX on sheets 10-12, 16-18, 22-24 and 28 of the figures. This seqeunce reads on SEQ ID No. 1 of the instant invention. On page 14, line 22+ the reference discloses and clearly suggests the conversion of the amino acid sequences into nucleic acid sequences to be used in the detection of further SDR candidates..

The only difference between the instant reference and the instant claims is that the claims are directed to nucleic acid sequences.

In view of the clear suggestion in the reference to convert the amino acid sequences to nucleic acid sequences, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to convert the amino acid sequences to nucleic acid sequences to be used in the detection of further SDR candidates.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh